REMARKS

The Examiner has required restriction under 35 U.S.C. §§ 121 and 372. The Examiner requires election of a single invention to which the claims must be restricted. In a telephone interview with the Examiner on July 2, 1997, Applicants provisionally elected the invention of Group I, claims 1-8 and 17-18, with traverse. Applicants hereby affirm the election and provide a grounds for traversal of this election requirement with regard to Groups I and II. According to 37 C.F.R. § 1.475(b)(1), unity of invention is found if claims are drawn to a product and a process specially adapted for the manufacture of said product. The invention of Group I, claims 1-8 and 17-18 are drawn to a peptide and compositions of the peptide. The Group II invention, claim 9, is directed to a method of making the same peptide. Therefore, unity of invention is believed present with regard to Groups I and II. Applicants, therefore, respectfully request inclusion of the Group II method and claim 9 in what is considered to be the present invention and respectfully request examination of claim 9 on the merits along with elected claims 1-8 and 17-18.

The Examiner rejected claims 1-8 and 17-18 under 35 U.S.C. § 112, second paragraph, for purported indefiniteness. The Examiner rejected claim 1 as indefinite for the recitation of "sequence identity." "Sequence identity" is a term well-known in the art. The identity is measured by aligning the two sequences under consideration, identifying the amino acids which are identical in the two alignments at the same position, counting them and calculating the sum as a percentage of the

total number of amino acids under consideration. In support of this definition of "sequence identity," Applicants performed an Internet search on the AltaVista search engine (http:\\www.altavista.com) on the term "sequence identity." The search indicated that 29,746 documents matched the query. Of the first ten matches, Applicants printed out the first three using the term "sequence identity" in context. In these printouts, "sequence identity," "identity" and "sequence homology" were used in an identical manner. In sum, the term "sequence identity" is well-known in the art and is used to refer to the degree of homology between two sequences.

The Examiner rejected claim 7 for indefiniteness for purported lack of clarity. Applicants do not amend the claim because it most accurately describes what was intended. As a preliminary matter, claim 7, originally claim 8, has now been amended to depend from claim 1, not claim 6.

Claim 1 describes the nature of the microbial peptide and its degree of homology with a mammalian stress protein. The microbial gene from which the peptide is derived must have 25% homology (or sequence identity) with a mammalian stress protein. At least 75 consecutive amino acids of this microbial stress protein gene must have at least 40% homology with the mammalian homologue. The peptide is 5-30 amino acids of the microbial protein. The peptide must include amino acids of a T-cell epitope corresponding to a T-cell epitope of a mammalian protein in a same relative position as a T-cell epitope of the mammalian protein. The peptide must also have at least 5 amino acids identical to amino acids in the same relative position of the

epitope of the mammalian stress protein and the epitope must have at least 4 consecutive amino acids identical with the corresponding mammalian stress protein amino acids. Therefore, claim 1 describes a peptide derived from a microbial stress protein having substantial homology to a mammalian stress protein and peptide including a T-cell epitope in a same relative position in the peptide as in the mammalian homologue; the epitope having substantial homology with the epitope of a mammalian stress protein.

Claim 7 provides the further limitation that the microbial peptide as claimed in claim 1 must not include an additional non-homologous T-cell epitope (that does not include a stretch of at least three consecutive amino acids which are identical to those in the corresponding mammalian stress protein). Claim 7 contemplates a microbial peptide having two T-cell epitopes, one of which has substantial identity with the mammalian stress protein epitope, the other not having sufficient homology with the mammalian stress protein T-cell epitope. It was found that the peptides are more effective when they are devoid of microbial T-cell epitopes which have low homology with mammalian counterparts. Therefore, Applicants respectfully request reconsideration of the rejection of claims 1 and 7 under 35 U.S.C. § 112, second paragraph.

The Examiner rejected claims 1-6 and 17-18 under 35 U.S.C. § 102(b) for purported anticipation by Oftung et al. ("the Oftung article"). The Oftung article discloses a microbial peptide, peptide 91-105 of *M. tuberculosis*. Applicants believe this rejection is without basis because the peptide 91-105 does

not contain a T-cell epitope of a mammalian stress protein. The Oftung article, in Table 1, on pp. 2750, discloses practically zero T-cell response for residues 91-105. This is confirmed by Figs. 3 and 4 in the present application, showing that the response to peptide 91-105 does not significantly differ from native controls. Plus further evidence

The Examiner rejected claims 1-4 and 17-18 under 35 U.S.C. § 102(b) for anticipation by European Patent No. 0 262 710 (the '710 patent). The '710 patent discloses antigen A, a gene isolated from *Mycobacterium bovis* that is substantially similar to the hsp65 protein of *M. tuberculosis* described in the present application. A 70mer peptide derived from the same protein is also disclosed in the '710 patent. In contrast, the claims of the present application are directed to specific 5-30mers of the hsp65 peptide. Furthermore, as disclosed throughout the specification and drawings of the present invention, the specifically defined 5-30mer peptides provide superior results as compared to the complete hsp65 protein and large fragments thereof that do not comply with the claimed selection criteria. Therefore, the disclosures of the '710 patent do not anticipate the claims of the present invention. Therefore, Applicants respectfully request reconsideration of the rejections of claims 1-6 and 17-18 under 35 U.S.C. § 102(b). Comparison to Data

The Examiner rejected claim 8 under 35 U.S.C. § 103 as being obvious over Oftung or the '710 patent in view of U.S. Patent No. 5,643,873 (the '873 patent). As a preliminary matter, Applicants hereby amend claim 8 to depend from claim 7 as a result of the Examiner's renumbering of the claims. The Examiner

alleges that "the '873 patent teaches that peptide mimetics are art recognized as useful for having the same or similar biological activity as the native peptide, but with more favorable activity than the peptide with respect to solubility, stability and susceptibility to hydrolysis and proteolysis." Because the peptides of claim 1 are neither anticipated by nor obvious in view of the Oftung article and/or the '710 patent, mimetics of the peptide would not be obvious. Therefore, Applicants respectfully request reconsideration of the rejection of claim 8 under 35 U.S.C. § 103.

Applicants believe that claims 1-8 and 17-18 define over the prior art of record and are in proper form for allowance. Applicants, therefore, respectfully request allowance of claims 1-8 and 17-18.

Respectfully submitted,

WEBB ZIESENHEIM BRUENING LOGSDON
ORKIN & HANSON, P.C.

By _____

Barbara E. Johnson
Registration No. 31,198
Attorney for Applicants
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818
Telephone: 412-471-8815
Facsimile: 412-471-4094